COVID-19 Therapeutics Information Brief

March 9, 2022

Changes to the document from the previous version are highlighted in yellow.

IMPORTANT/NEW COVID-19 Therapeutics Information

- Reporting Evusheld Doses in HPoP
- Allocation Cadence Changes for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Antivirals
- Therapeutic Reporting Reminder
- Reporting Wastage Guidance
- Allocations for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Oral Antivirals
- Disposal of Extra Doses of Nirmatrelvir from Blister Packs for Patients with low eGF
- COVID-19 Therapeutics Information Resources

Reporting Evusheld Doses in HPoP

Evusheld now should be administered as an initial dose of 600 mg. Individuals who already received the previously authorized initial 300 mg dose should receive a second Evusheld dose as soon as possible.

Reporting doses of Evusheld in HPoP: Healthcare providers are required to report on-hand and usage data of Evusheld **daily** in HPoP.

- Report on-hand inventory based on the number of 300 mg cartons.
- Healthcare providers should not edit Evusheld inventory in HPOP to account for the change in the initial dose. Regardless of the Evusheld dose(mg) administered, a carton or "dose" is 300 mg.
- The initial "dose" administered is 600mg or two 300mg cartons. For the purpose of reporting in HPoP, healthcare providers should report by numbers of cartons. Two cartons administered to a patient would be reported as two "doses" given.
- The catch up "dose" is 300mg or one carton. For the purpose of reporting in HPoP, report by numbers of cartons. One carton administered for a catch up dose would be reported as one "dose" given.

Evusheld Resources:

- Fact Sheet for Healthcare Providers
- Healthcare Provider Letter
- Fact Sheet for Patient's, Parents, and Caregivers

As part of the EUA, FDA requires health care providers who prescribe Evusheld to report all medication errors and serious adverse events considered to be potentially related to Evusheld through FDA's MedWatch Adverse Event Reporting program. Providers can complete and submit the report online; or download and complete the form, then submit it via fax at 1-800-FDA-0178.

If you need assistance with HPoP, please contact C19therapeutics@idph.iowa.gov.

Allocations Cadence Changes for Monoclonal Antibodies, PReP Treatment and Antivirals

Antivirals will shift to a weekly allocation cycle. This will align with the weekly allocation cadence for monoclonal antibodies (Bebtelovimab and sotrovimab) and the pre-exposure prophylaxis treatment (Evusheld). The ordering cadence will be as follows:

- Allocation Survey Sent - Monday
- Allocation Survey Due Back to IDPH - Tuesday at 4:00pm
- Allocation Ordered in Federal System - Thursday
- Allocation Amount Notification from IDPH to healthcare providers - Thursday

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Therapeutic Reporting Reminder

Sites receiving monoclonal antibodies, pre-exposure prophylaxis treatment, or oral antivirals MUST comply with federal reporting requirements.

Failure to comply with reporting requirements may result in the loss of COVID-19 therapeutic providers status and removal of COVID-19 therapeutic products. **Reporting requirements are as follows:**

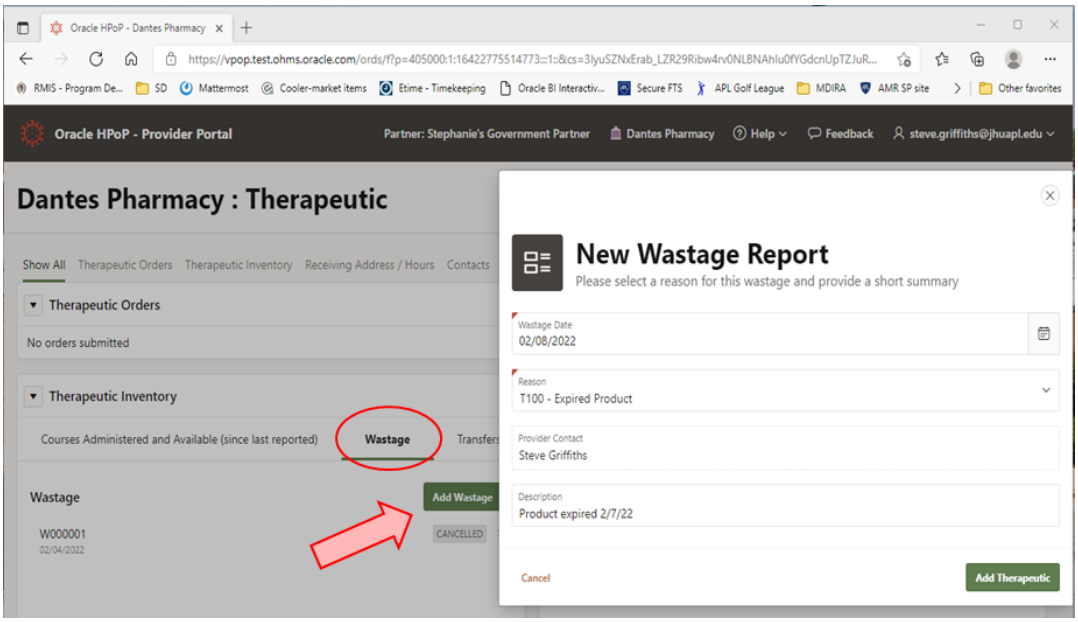
- Monoclonal antibodies (REGEN-COV, bamlanivimab/etesevimab, sotrovimab): Report on-hand and usage data **every Wednesday** in NHSN (for long-term care facilities) or Teletracking (for all other sites including hospitals).
- Pre-exposure prophylaxis treatment and oral antivirals (Evusheld, Paxlovid, Molnupiravir and Bebtelovimab): Report on-hand and usage data **daily** in HPoP. If you need assistance with HPoP, please contact C19therapeutics@idph.iowa.gov.

Reporting Wastage Guidance

In the Provider or Partner Portal, a new tab has been added in the Therapy Inventory section – Wastage. Wastage will be reported for all therapeutic products except Sotrovimab. The following steps outline the reporting of wastage of COVID-19 Therapeutics in HPoP:

- Choose wastage, then select the green "Add Wastage" button. A blank report appears.
- Enter the wastage date, the reason for the wastage (expired, damaged, temp excursion, or other).
    - A provider contact may be chosen, or is predetermined.
    - A description can be added.

- Upon selecting Add Therapeutic, a second window will open allowing details for each line in the wastage report to be entered. Select the therapeutic from drop down, enter the number of courses, a lot number and the lot expiration date.



Allocations for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Antivirals

	Iowa Statewide Allocations for the week Monday, February 28, 2022 - Sunday, March 6, 2022			
mAbs		Oral AVs		PrEP
Bebtelovimab	Sotrovimab	Mulnupiravir	Paxlovid	EVUSHELD
685 courses	**726 doses**	**984 courses**	**940 courses**	**1896 doses**

Therapeutic product requests from Iowa healthcare providers continue to greatly exceed the number of therapeutic courses allocated to Iowa by the federal government. HHS has clearly stated the intent to decrease the allocation of therapeutics, specifically monoclonals, as Omicron becomes dominant across states. Iowa continues to see a decrease in allocation numbers from the federal government for BAM/ETE and REGEN-COV therapeutics. Please refer to the below talking points to ensure healthcare providers are up-to-date with the current therapeutics allocation process.

- The minimum order quantity for Molupiravir is 24 courses.
- The Iowa Department of Public Health (IDPH) is working to prioritize allocations of therapeutic products based on the regional trends of the variants.
- County by county variant rates *are not* being considered in therapeutic requests due to available data.

- **Allocations will not include bamlanivimab plus etesevimab and casirivimab plus imdevimab (REGEN-COV).**
- **Healthcare providers should NOT expect to receive regular (or any) allocations of therapeutic products.**
- **IDPH encourages entities who do receive allocations of therapeutic products to notify and work with prescribers and LPHAs on the availability of therapeutic products in the community.**
- The Therapeutic Information Brief will continue to provide the most up-to-date information regarding the availability of therapeutic products and ordering cadence.
- The Department of Health and Human Services has released a COVID-19 Therapeutics locator. Monoclonals are not well populated yet largely because of availability across the state/nation.
    - The locations displayed in the locator are based on stock on hand as reported by the location and are not a guarantee of availability.
    - Locations that report fewer than 5 courses of the selected therapeutic are not displayed. All therapeutics identified in the locator must be used in alignment with the terms of the respective product's EUA.
    - **This therapeutics locator is intended for provider use, as the included therapies require a prescription by a licensed and authorized provider. Patients should not contact locations directly.**

Disposal of Extra Doses of Nirmatrelvir from Blister Packs for Patients with low eGFR

Per Dear HCP Letter endorsed by the FDA, in reference to moderate renal impairment dosing adjusted to 150 mg nirmatrelvir with 100 mg ritonavir taken twice daily for 5 days: "Pharmacists should discard the removed tablets per state requirements or local guidelines." It is recommended providers dispose of the medication via the workflows used to dispose of expired or other waste purposes. The HCP letter and Pharmacist Instructions are available at: https://www.covid19oralrx-hcp.com/resources

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COVID-19 Therapeutics Information Resources

- **COVID-19 Therapeutics Call Center -** IDPH has established a COVID-19 Therapeutics Call Center. To reach the COVID-19 Therapeutics Call Center, call **515-281-7317**.
- **COVID-19 Therapeutics Email -** IDPH has set up a COVID-19 Therapeutics Email to respond specifically to questions from healthcare providers regarding COVID-19 therapeutics. Therapeutic questions can be emailed to: C19Therapeutics@idph.iowa.gov
    - NOTE: **The COVID-19 Therapeutics Call Center and Email are intended for healthcare providers only.**
- **COVID-19 Therapeutics Table-** IDPH has developed a table of therapeutic products available for the treatment or prevention of COVID-19.